DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 27 2000

Erich Jaeger GmbH
c/o Mr. Earl Draper
Sensormedics
22705 Savi Ranch Parkway
Yorba Linda, CA 92887-4645

Re: K000396
Trade Name: ApnoeScreen Pro
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: November 13, 2000
Received: November 20, 2000

Dear Mr. Draper:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have

under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K000396

Device Name: APNOESCREEN PRO

Indications For Use:

The ApnoeScreen Pro is a portable physiological signal recording device intended to be used for testing patients suspected of have sleep-related breathing disorders. It is intended to be used under the direction of a physician. The device may be used in the home, clinic, doctor's office, or hospital. The system is to be used for testing patients from 7 years upwards.
The ApnoeScreen Pro, or any of the accessories supplied with it, is not to be used, alone or in combination, as an apnea monitor or as a component in an apnea monitoring System.
The ApnoeScreen Pro, or any of the accessories supplied with it, is not to be used, alone or in combination, as a life support device, a life support System, or as a critical component in a life support device or life support system.
The following caution label appears in the appendix on page 1 of the Safety Precautions of the ApnoeScreen Pro Instruction Manual (orange pages): ,"Federal (U.S.A) law restricts this device to sale by or on the order of a physician."

Conditions:
The system is only to be used in-door. The ambient conditions are

- Temperature: +10 to +40 degrees C
- Relative humidity: 30 to 75 % non-condensing
- Barometric pressure: 700 to 1060 mBar.

June-12-2000
Dr. Jürgen Reinstädtler
Product Manager

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office~~ of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K000396

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)